KCC 4749.2
K-C 16,858.2
PATENT

REMARKS

Claim 58 has been amended herein in this Amendment A to correct a typographical error. Support for the amendment to claim 58 can be found in the specification on page 21, paragraph 0064. No new matter has been added by this amendment. After entry of this Amendment A, claims 1, 11, 14-20, and 22-68 will be pending in this case. Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of Claim 58 Under 35 U.S.C. §112, Second paragraph

Reconsideration is requested of the rejection of claim 58 under 35 U.S.C. §112, Second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 58 recites the variable R^{22} as comprising an amine selected from the group consisting of lauramine, lauramino, propionic acid, etc. Propionic acid fails to contain an amine group.

Applicants have amended claim 58 to correct this typographical error. Claim 58, as amended, now requires the variable R^{22} to comprise an amine selected from the group consisting of lauramine, lauramino propionic acid, etc. Support for the amendment can be found on page 21, paragraph 0064.

As claim 58 has been amended, the rejection of claim 58 under 35 U.S.C. §112, Second paragraph should be withdrawn as moot.

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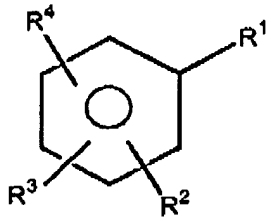
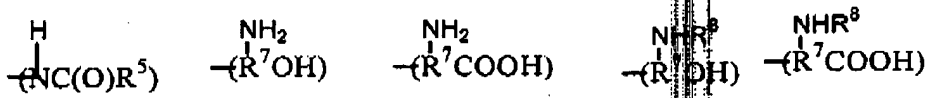
2. Rejection of Claims 1, 11, 12, and 15 Under 35 U.S.C. §102(b)

Reconsideration is requested of the rejection of claims 1, 11, 12, and 15 under 35 U.S.C. §102(b) as being anticipated by Ritchey (U.S. 4,560,549).

Claim 1 is directed to an exoprotein inhibitor for inhibiting the production of exoproteins from Gram positive bacteria in and around the vagina. The exoprotein inhibitor comprises a non-absorbent substrate for insertion into a vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche. The non-absorbent substrate having deposited thereof an effective amount of a first active ingredient having the general formula:

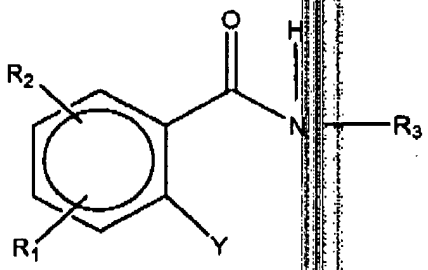


wherein R^1 is selected from the group consisting of H, $-COR^5$, $-OR^5$, $-R^6C(O)H$, $-R^6COOH$, $-OR^6COOH$, $-C(O)NH_2$,



and NH_2 and salts thereof; R^5 is a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^6 is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^7 is a trivalent saturated or unsaturated aliphatic hydrocarbyl moiety; R^8 is a monovalent substituted or unsubstituted saturated or unsaturated aliphatic hydrocarbyl moiety which may or may not be interrupted with hetero atoms; R^2, R^3, and R^4 are independently selected from the group consisting of H, OH, COOH, and $-C(O)R^9$; R^9 is hydrogen or a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety. The first active ingredient is effective in inhibiting the production of exoprotein from Gram positive bacteria. As noted by the Office, Applicants have elected the species $C(O)NH_2$ for initial examination.

Ritchey discloses a topically and systemically administered anti-inflammatory composition for human and for veterinary consumption. The anti-inflammatory composition has the general formula:



wherein R_1, R_2, and R_3 are defined hydrocarbon attachments and Y is -OH or a phenolic ester group derived from the reaction of such -OH group with a carboxylic acid halide or anhydride.

Preferably, R_3 is selected from the group consisting of thiazol-2-yl, benzothiazol-2-yl, and R_4-substituted phenyl. Alternatively, $-R_3$ may simply be any aryl or heteroaryl group or secondary amido ligand $-CH_2-R_6$ wherein $-R_6$ is -H or an attachment of up to 24 carbon atoms of the same description as $-R_1$ or $-R_2$ involving the same linking groups between itself and the methylene group directly attached to the amido nitrogen atom.

The compositions of Ritchey can take the form of ointments, solid sticks, tablets, capsules, injectable solutions and suspension, ear drops, eye drops, nose drops, douches, suppositories, enemas, liniments, gels, lotions, shampoos, soaps, creams, solutions, aerosols, pads, plasters, bandages, dressings, and catamenial and non-catamenial tampons. These compositions are useful in relieving pain or inflammation as well as microbial infections in mammals when applied topically to the skin or affected organs or when administered systemically.

Significantly, Ritchey fails to disclose a non-absorbent substrate having deposited thereon an effective amount of a first active ingredient having the formula as required in claim 1. This is a requirement of claim 1 and is a significant aspect of Applicants' invention. For the composition of Ritchey to anticipate claim 1 (and specifically, the species elected by Applicants), R_3 in the composition of Ritchey would have to be hydrogen. Despite the assertion by the Office that Formula I reads on the elected species, the composition of Ritchey does not disclose any compositions where R_3 is H, and as such, cannot

read on the elected species of claim 1, which requires an $-NH_2$ group.

As stated in M.P.E.P. §2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Since Ritchey fails to disclose an exoprotein inhibitor comprising a non-absorbent substrate having deposited thereon an effective amount of a first active ingredient with the general formula of claim 1, Ritchey fails to disclose each and every limitation of claim 1. As such, claim 1 is novel over the Ritchey reference.

Claims 11, 12[1], and 15 depend directly from claim 1. As such, claims 11, 12, and 15 are patentable for the same reasons as claim 1 set forth above, as well as for the additional limitations they require.

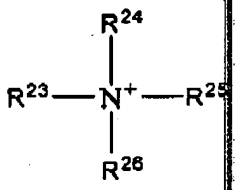
3. Rejection of Claims 16-19 and 63-68 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 16-19 and 63-68 under 35 U.S.C. §103(a) as being unpatentable over Ritchey (U.S. 4,560,549).

Claims 16-19 and 63-68 depend directly or indirectly from claim 1, which is discussed above. Claims 16-18 are further directed to the amount of first active ingredient present on the

[1] Applicants note that the Office has rejected claim 12 as being anticipated by the Ritchey reference. Claim 12 has been withdrawn from consideration as being directed to a non-elected invention. If pending, however, since claim 12 depends from

non-absorbent substrate. Claim 19 further requires the exoprotein inhibitor to comprise a pharmaceutically active material selected from the group consisting of antimicrobials, antioxidants, anti-parasitic agents, antipruritics, astringents, local anaesthetics, and anti-inflammatory agents. Claims 63-68 further require the exoprotein inhibitor to comprise an effective amount of a second active ingredient having the general formula:



wherein R^{23} is an alkyl group having from 8 to about 18 carbon atoms and R^{24}, R^{25}, and R^{26} are independently selected from the group consisting of hydrogen and alkyl group having from 1 to about 18 carbon atoms and which can have one or more substitutional moieties selected from the group consisting of hydroxyl, carboxyl, carboxyl salts, and imidazoline. Claim 1 is patentable for the reasons set forth above. In particular, the Ritchey reference fails to disclose an exoprotein inhibitor comprising a non-absorbent substrate having deposited thereon an effective amount of a first active ingredient having the general formula of claim 1.

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claim 1, claim 12 would be patentable for the same reasons as claim 1 set forth above.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under number (1) and/or (2) above, as Ritchey fails to show each and every limitation of Applicants' invention and there is no motivation or suggestion to modify Ritchey to arrive at each and every limitation.

As noted above, Ritchey fails to teach or suggest a non-absorbent substrate having deposited thereon an effective amount of a first active ingredient with the general formula as required in the present invention. Further, Ritchey fails to suggest or disclose any motivation to one skilled in the art to modify its anti-inflammatory composition to have the general formula as required in the present invention. Specifically, Ritchey uses its anti-inflammatory composition to relieve dermal inflammation or painful conditions due to eczema, psoriasis, seborrheic dermatitis, reactions due to poison ivy, poison oak and stinging nettles, etc., and sunburns, thermal burns, other electromagnetic radiation burns, insect and kindred bites and stings. The present invention, however, is directed to inhibiting the production of exoproteins, such as TSST-1, from Gram positive bacteria in and around the vagina. As such, Ritchey simply fails to recognize or disclose the problem solved

by the present invention. As Ritchey is directed to a separate problem from the present invention, one skilled in the art would not, and could not, be motivated to modify the anti-inflammatory compositions of Ritchey to arrive at the first active ingredient having the general formula as required by the present invention. As such, claim 16-19 and 63-68 are patentable over the Ritchey reference.

4. Rejection of Claims 22-31 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 22-31 under 35 U.S.C. §103(a) as being unpatentable over Ritchey (U.S. 4,560,549) in view of Syverson (U.S. 5,612,045) or Syverson in view of Ritchey.

Claims 22-31 depend directly or indirectly on claim 1, which is discussed above. Claims 22-31 are further directed to the exoprotein inhibitor comprising an effective amount of a second active ingredient having the general formula:

$$R^{10}——O——R^{11}$$

wherein R^{10} is a straight or branched alkyl or straight or branched alkenyl having from 8 to about 18 carbon atoms and R^{11} is selected from the group consisting of an alcohol, a polyalkoxylated sulfate salt and a polyalkoxylated sulfosuccinate salt. Claim 1 is patentable for the reasons set forth above. In particular, the Ritchey reference fails to

disclose a non-absorbent substrate having deposited thereon an effective amount of a first active ingredient having the general formula of claim 1.

Syverson fails to overcome the above shortcomings. Specifically, Syverson fails to disclose a first active ingredient having the general formula of claim 1. Additionally, Syverson fails to disclose a combination of the first active ingredient of claim 1 and an ether as required in claims 22-31.[2]

Based on the foregoing, Syverson fails to remedy the shortcomings of the Ritchey reference. As such, the addition of Syverson does not make claims 22-31 obvious in view of the Ritchey reference.

5. Rejection of Claims 32-47 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 32-47 under 35 U.S.C. §103(a) as being unpatentable over Ritchey (U.S. 4,560,549) and Syverson (U.S. 5,612,045) in view of Yahiaoui et al. (U.S. 6,767,508).

Claims 32-47 depend directly or indirectly on claim 1, which is discussed above. Claim 32 further requires the ether compound on claim 22 to be present in an amount of from about 0.005 millimoles per gram of non-absorbent substrate to about 0.2 millimoles per gram of non-absorbent substrate. Claim 33 further requires the exoprotein inhibitor to comprise a pharmaceutically active material selected from the group

consisting of antimicrobials, antioxidants, anti-parasitic agents, antipruritics, astringents, local anaesthetics, and anti-inflammatory agents. Claims 34-47 are further directed to the exoprotein inhibitor comprising an effective amount of a second active ingredient comprising an alkyl polyglycoside effective in substantially inhibiting the production of exoprotein from Gram positive bacteria. Claim 1 is patentable for the reasons set forth above. In particular, the Ritchey and Syverson references fail to disclose an exoprotein inhibitor comprising a non-absorbent substrate having deposited thereon an effective amount of a first active ingredient having the general formula of claim 1.

It is respectfully submitted that the Yahiaoui et al. patent is not prior art against this pending application under 35 U.S.C. §103(a). The Yahiaoui et al. reference cited by the Office has a priority date of November 28, 2000 based on its 35 U.S.C. §102(e)(1) application date.[3] However, as stated in 35 U.S.C. §103(c), prior art which qualifies only under subsection (e) of section 102 does not preclude patentability where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. The Yahiaoui et al. reference has been assigned to Kimberly-Clark Worldwide,

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[2] Applicants note that the Office asserts that Syverson teaches non-absorbent articles such as tampons. Applicants respectfully point out that the tampons of Syverson are absorbent articles.

[3] 35 U.S.C. §102(e)(1) applies to an invention described in "an application for patent, published under §122(b) by another filed in the United States before the invention by the applicant for patent…."

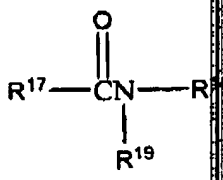
Inc. Furthermore, the instant application has also been assigned to Kimberly-Clark Worldwide, Inc. As evidence of these assignments, enclosed herewith is the following: (1) electronic copy of Assignment for the Yahiaoui et al. reference, which sets forth that both inventors of this reference have assigned their rights to Kimberly-Clark Worldwide, Inc.; and (2) the Notice of Recordation of Assignment Document and Assignment for the instant application indicating that all inventors have assigned their rights to Kimberly-Clark. As such, Applicants assert that Yahiaoui et al. cannot be a proper basis of rejection of the claims of the present application as Yahiaoui et al. cannot be considered as prior art.

Because the Yahiaoui et al. reference is cited improperly as prior art, this rejection under 35 U.S.C. §103(a) is improper and should be withdrawn. As such, claims 32-47 are patentable over Ritchey and Syverson in view of Yahiaoui et al.

6. Rejection of Claims 48-55 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 48-55 under 35 U.S.C. §103(a) as being unpatentable over Ritchey (U.S. 4,560,549) in view of Syverson (U.S. 5,685,872).

Claims 48-55 depend directly or indirectly on claim 1, which is discussed above. Claims 48-55 are further directed to the exoprotein inhibitor comprising an effective amount of a second active ingredient having the general formula:



wherein R^{17}, inclusive of the carbonyl carbon, is an alkyl group having 8 to 18 carbon atoms, and R^{18} and R^{19} are independently selected from hydrogen or an alkyl group having from 1 to about 12 carbon atoms which may or may not be substituted with groups selected from ester groups, ether groups, amine groups, hydroxyl groups, carboxyl groups, carboxyl salts, sulfonate groups, sulfonate salts, and mixtures thereof. Claim 1 is patentable for the reasons set forth above. In particular, the Ritchey reference fails to disclose an exoprotein inhibitor comprising a non-absorbent substrate having deposited thereon an effective amount of a first active ingredient having the general formula of claim 1.

Syverson fails to overcome the above shortcomings. Specifically, Syverson fails to disclose a first active ingredient having the general formula of claim 1. Additionally, Syverson fails to disclose a combination of the first active ingredient of claim 1 and the second active ingredient of claims 48-55.

As such, neither of the cited references teaches or suggests an exoprotein inhibitor comprising a non-absorbent substrate having deposited thereon a first active ingredient having the general formula as required in the present invention.

As such, the addition of Syverson does not make claims 48-55 obvious in view of the Ritchey reference.

7. Rejection of Claims 56-62 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 56-62 under 35 U.S.C. §103(a) as being unpatentable over Ritchey (U.S. 4,560,549) in view of Syverson (U.S. 5,618,554).

Claims 56-62 depend directly or indirectly on claim 1, which is discussed above. Claims 56-62 are further directed to the exoprotein inhibitor comprising an effective amount of a second active ingredient having the general formula:

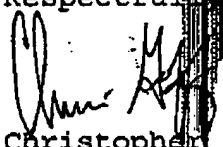
wherein R^{20} is an alkyl group having from about 8 to about 18 carbon atoms and R^{21} and R^{22} are independently selected from the group consisting of hydrogen and alkyl groups having from 1 to about 18 carbon atoms and which can have one or more substitutional moieties selected from the group consisting of hydroxyl, carboxyl, carboxyl salts, and imidazoline. Claim 1 is patentable for the reasons set forth above. In particular, the Ritchey reference fails to disclose an exoprotein inhibitor comprising a non-absorbent substrate having deposited thereon an

effective amount of a first active ingredient having the general formula of claim 1.

Syverson fails to overcome the above shortcomings. Specifically, Syverson fails to disclose a first active ingredient having the general formula of claim 1. Additionally, Syverson fails to disclose a combination of the first active ingredient of claim 1 and the second active ingredient of claims 56-62. As such, the addition of Syverson does not make claims 56-62 obvious in view of the Ritchey reference.

In view of the above, Applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Amendment A to Deposit Account Number 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

Respectfully Submitted,



Christopher M. Goff, Reg. No. 41,785
SENNIGER POWERS
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
314-231-5400

CMG/JMB/dhm

Via Facsimile (703) 872-9306